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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ira Tabas  
Serial No. : 10/767,749 Examiner: B.E. Bunner  
Filing Date : January 28, 2004 Art Unit: 1647  
For : METHODS FOR PREVENTING ACUTE CLINICAL  
VASCULAR EVENTS IN A SUBJECT

1185 Avenue of the Americas  
New York, New York 10036  
August 20, 2007

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following references which are listed on the attached Substitute Form PTO-1449 (**Exhibit A**). Copies of these references are attached hereto as **Exhibits 1-68**, respectively.

1. U.S. Application Serial No. 09/553,927 filed April 21, 2000, on behalf of Tabas et al. (now abandoned) (**Exhibit 1**);
2. U.S. Patent Application Publication No. US2003/0235878 A1 published December 25, 2003, on behalf of Tabas et al. (now abandoned);
3. PCT International Application No. PCT/US2001/012877, filed April 20, 2001, publication No. WO 2001/080715 A3, published

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- November 1, 2001 on behalf of The Trustees of Columbia University in the City of New York (**Exhibit 2**);
4. PCT International Application No. PCT/US2003/013164, filed April 30, 2003, publication No. WO 2003/092467 A3, published November 13, 2003 on behalf of The Trustees of Columbia University in the City of New York (**Exhibit 3**);
  5. December 22, 2006 International Preliminary Examination Report issued in connection with PCT International Application No. PCT/US2001/12877, filed April 20, 2001 (**Exhibit 4**);
  6. Aikawa, K., et al. (1994) "Structure-specific Inhibition of Lysosomal Cholesterol Transport in Macrophages by Various Steroids," *Biochim. Biophys. Acta.* 1213: 127-134 (**Exhibit 5**);
  7. Arends, M.J., et al. (1991) "Apoptosis: Mechanisms and Roles in Pathology," *Int. Rev. Exper. Pathol.* 32: 223-254 (**Exhibit 6**);
  8. Basu, S.K., et al. (1976) "Degradation of Cationized Low Density Lipoprotein and Regulation of Cholesterol Metabolism in Homozygous Familial Hypercholesterolemia Fibroblasts," *Proc. Natl. Acad. Sci. U.S.A.* 73: 3178-3182 (**Exhibit 7**);
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The subject application is a continuation-in-part of and claims benefit of U.S. Serial No. 09/553,927, filed April 21, 2000, and U.S. Serial No. 10/426,415, filed April 30, 2003, which claims priority of U.S. Provisional Application No. 60/376,984, filed April 30, 2002, and U.S. Provisional Application No. 60/494,721, filed August 11, 2003.

A copy of U.S. Serial No. 09/553,927 is attached hereto as **Exhibit 1**. An Office Action was issued on May 7, 2001 in connection with U.S. Serial No. 09/553,927. A copy is attached hereto as **Exhibit 60**. Above-listed references 72-80 were cited in the May 7, 2001 Office Action. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120. A Final Office Action was issued on March 8, 2002 in connection with U.S. Serial No. 09/553,927. A copy is attached hereto as **Exhibit 61**. An Advisory

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Action was issued on September 9, 2002 in connection with U.S. Serial No. 09/553,927. A copy is attached hereto as **Exhibit 62**. An Office Action was issued on July 29, 2003 in connection with U.S. Serial No. 09/553,927. A copy is attached hereto as **Exhibit 63**.

U.S. Serial No. 10/426,415 is a published application listed above as reference 2. Accordingly, pursuant to 37 C.F.R. §1.98(a)(ii) a copy of this application is not required to be provided to the United States Patent and Trademark Office. An Office Action was issued on September 21, 2005 in connection with U.S. Serial No. 10/426,415. A copy is attached hereto as **Exhibit 64**. Above-listed reference 149 was cited in the September 21, 2005 Office Action. An Office Action was issued on March 24, 2006 in connection with U.S. Serial No. 10/426,415. A copy is attached hereto as **Exhibit 65**. Above-listed references 81-83 were cited in the March 24, 2006 Office Action. A Final Office Action was issued on October 4, 2006 in connection with U.S. Serial No. 10/426,415. A copy is attached hereto as **Exhibit 66**. Above-listed reference 84 was cited in the October 4, 2006 Final Office Action. Accordingly, under 37 C.F.R. §1.98(d) copies of references 81-84 and 149 are not required to be provided to the United States Patent and Trademark Office, since they were previously cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

Above-listed references 85-93 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on April 16, 2001 in connection with U.S. Serial No. 09/553,927, filed April 21, 2000. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark

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Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

Above-listed references 94-148 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on September 4, 2003 in connection with U.S. Serial No. 10/426,415, filed April 30, 2003. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

PCT International Application No. PCT/US2001/012877, filed April 20, 2001, is a related foreign application, which also claims priority of U.S. Serial No. 09/553,927, filed April 21, 2000. A copy of PCT International Application No. PCT/US2001/012877 is attached hereto as **Exhibit 2**.

An International Search Report was issued on December 19, 2003 in connection with PCT International Application No. PCT/US2001/012877, filed April 20, 2001. A copy of the Search Report is attached hereto as **Exhibit 67**. Above-listed reference 35 (copy attached hereto as **Exhibit 34**) was cited in the Search Report.

An International Preliminary Examination Report was issued on December 22, 2006 in connection with PCT International Application No. PCT/US2001/012877, filed April 20, 2001. A copy of the Report is attached hereto as **Exhibit 4**.

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PCT International Application No. PCT/US2003/013164, filed April 30, 2003, is a related foreign application, which also claims priority of U.S. Provisional Application No. 60/376,984, filed April 30, 2002. A copy of PCT International Application No. PCT/US2003/013164 is attached hereto as **Exhibit 3**.

An International Search Report was issued on March 15, 2004 in connection with PCT International Application No. PCT/US2003/013164, filed April 30, 2003. A copy of the Search Report is attached hereto as **Exhibit 68**. Above-listed references 70 and 71 were cited in the Search Report. These references are published U.S. applications. Accordingly, pursuant to 37 C.F.R. §1.98(a)(ii) copies of these applications are not required to be provided to the United States Patent and Trademark Office.

Applicant requests that the Examiner review the documents listed above and make them of record in the subject application.

Pursuant to 37 C.F.R. 1.97(c)(2), the required fee for filing this Information Disclosure Statement is ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) and a check for this amount is enclosed.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

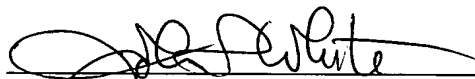
No fee, other than the enclosed \$180.00 fee, is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required,



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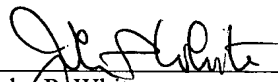
authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

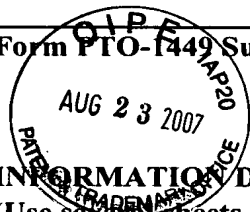


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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE STATEMENT**  
(Use several sheets if necessary)

Application Number	10/797,749
Filing Date	January 28, 2004
First Named Inventor	Ira Tabas
Art Unit	1647
Examiner Name	B.E. Bunner
Attorney Docket No.	0575/60921-A/JPW/MVM

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	US 09/553,927	04-21-2000	Tabas et al.
	2	US 2003-0235878 A1	12-25-2003	Tabas et al.
	70	US 2002-0128266 A1	09-12-2002	Campbell et al.
	71	US 2002-0146681 A1	10-10-2002	Rothblat

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code*Number*Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
	3	WO 2001/080715 A3	11-01-2001	The Trustees of Columbia University in the City of New York	
	4	WO 2003/092467 A3	11-13-2003	The Trustees of Columbia University in the City of New York	

<b>EXAMINER SIGNATURE</b>	<b>DATE CONSIDERED</b>
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Applicants: Ira Tabas  
U.S. Serial No.: 10/767,749  
Filed: January 28, 2004  
Exhibit A

<b>Form PTO-1449 Substitute</b> <b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>  <b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)	<b>Application Number</b>	10/797,749	
	<b>Filing Date</b>	January 28, 2004	
	<b>First Named Inventor</b>	Ira Tabas	
	<b>Art Unit</b>	1647	
	<b>Examiner Name</b>	B.E. Bunner	
		<b>Attorney Docket No.</b>	0575/60921-A/JPW/MVM

### NON PATENT LITERATURE DOCUMENTS

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	5	December 22, 2006 International Preliminary Examination Report issued in connection with PCT International Application No. PCT/US2001/12877, filed April 20, 2001	
	6	Aikawa, K., et al. (1994) "Structure-specific Inhibition of Lysosomal Cholesterol Transport in Macrophages by Various Steroids," <i>Biochim. Biophys. Acta</i> 1213: 127-134	
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	28	Kruth, H.S. (1985) "Subendothelial Accumulation of Unesterified Cholesterol: An Early Event in Atherosclerotic Lesion Development," <i>Atherosclerosis</i> 57: 337-341			
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<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)				<b>First Named Inventor</b>	<b>Ira Tabas</b>
				<b>Art Unit</b>	<b>1647</b>
				<b>Examiner Name</b>	<b>B.E. Bunner</b>
				<b>Attorney Docket No.</b>	<b>0575/60921-A/JPW/MVM</b>
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	137	Yancey, P.G., et al. (1996) "Cellular cholesterol efflux mediated by cyclodextrins. Demonstration Of kinetic pools and mechanism of efflux," <i>J. Biol. Chem.</i> 271: 16026-16034	
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